UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF TEXAS

AUSTIN DIVISION

In re CASSAVA SCIENCES, INC. SECURITIES LITIGATION	§	Master File No. 1:21-cv-00751-DAE
	§	CLASS ACTION
This Document Relates To:	§	
ALL ACTIONS	§	

PLAINTIFFS' OPPOSITION TO MOTION TO DISMISS CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Unless otherwise noted, all defined terms have the same meaning as set forth in the Consolidated Complaint for Violations of the Federal Securities Laws (ECF 68) (the "Complaint"), and are provided in the below chart for convenience.

Term	Definition
"¶__" or "¶¶__"	All "¶__" or "¶¶__" are references are to the Complaint unless otherwise indicated.
"§__" or "§§__"	"§__" or "§§__" are internal references to particular sections within this brief unless otherwise noted.
"AAIC"	Alzheimer's Association International Conference
"Barbier"	Cassava's founder and CEO, Remi Barbier
"Cassava" or the "Company"	Cassava Sciences, Inc.
"Citizen Petition"	The petition, dated August 18, 2021, sent to the FDA on behalf of Drs. David Bredt and Geoffrey Pitt regarding Cassava's primary product candidate, simufilam, and related supplements.
The "Class"	All purchasers or acquirers of Cassava securities during the Class Period who were damaged thereby
"Class Period"	The time period between September 14, 2020 and July 26, 2022, inclusive
"CTAD"	Clinical Trials on Alzheimer's Disease
"CUNY"	City University of New York
"Defendants"	Cassava and the Individual Defendants
"DOJ"	United States Department of Justice
"Exchange Act"	Securities Exchange Act of 1934
"FDA"	United States Food and Drug Administration
"FOIL"	Freedom of Information Law
"Individual Defendants"	Defendants Remi Barbier, Dr. Lindsay Burns, Nadav Friedmann, and Eric J. Schoen
"Mot." or "Motion"	Motion to Dismiss Plaintiffs' Consolidated Complaint for Violations of the Federal Securities Laws (ECF 81)
"NIH"	National Institutes of Health
"Pain Therapeutics"	Pain Therapeutics, Inc.
"Plaintiffs"	Lead Plaintiff Mohammad Bozorgi and additional plaintiffs Ken Calderone and Manohar K. Rao
"PSLRA"	Private Securities Litigation Reform Act of 1995
"Rule"	Federal Rule of Civil Procedure

Term	Definition
"Quanterix"	Quanterix Corp.
"SEC"	United States Securities and Exchange Commission

I. INTRODUCTION

Plaintiffs' Complaint readily meets the pleading standards for Exchange Act claims. Plaintiffs allege that, throughout the Class Period, Defendants engaged in a scheme to materially mislead investors regarding the prospects for Cassava's primary drug candidate, simufilam. Defendants touted Cassava's pre-clinical and clinical studies to justify the continued commercial development of simufilam, but concealed the extensive data manipulation, significant anomalies, and conflicts of interest undermining the validity of the research. These were not inadvertent errors. Defendants deliberately manipulated clinical data by using image processing software, such as Photoshop, and other means, to alter or duplicate images in multiple journal articles and concealed adverse facts. Simply put, Defendants falsified data to make the research results fit the hypothesis. By spreading false and misleading information, Defendants inflated Cassava's stock price.

The response to these allegations has been swift. The DOJ has opened a criminal investigation, and the SEC and NIH have also initiated fraud investigations. Numerous scientific journals that published Cassava's results have issued retractions and expressions of concern over the data. Scientists all over the world were "stunned" and "shocked" by Cassava's "deliberate" actions, and have verified that the data was manipulated. Defendants' motive was simple. By misrepresenting the research results, Defendants stood to reap hundreds of millions of dollars' worth of cash bonuses tied to short-term increases in Cassava's stock. Defendants also pumped up Cassava's stock price to raise hundreds of millions of dollars of operating capital ***needed*** to fund simufilam's continued development.

The truth began to be revealed, however, when a "Citizen Petition" to the FDA by two scientist-turned-investors raised "grave concerns" regarding "the quality and integrity of the laboratory-based studies surrounding" simufilam. The pair predicted that Cassava's stock price would fall when those concerns came to light, and when the Citizen Petition was disclosed, the Company's share price plummeted nearly 40% on heavy trading.

In their Motion, Defendants insist that the Citizen Petition's findings cannot be credited because the petition amounts to a "short seller report" containing only "unproven" or "unadjudicated" "allegations" that may not be relied upon to plead a securities claim. Mot. at 1-3. But Plaintiffs have done much more than just parrot allegations from the Citizens Petition. Plaintiffs have established that the allegations in the Citizen Petition have been ***independently corroborated and verified*** by the foremost experts in the field, based not on "rank speculation" (*id.*), but on the analysis of Cassava's ***very own documents and data***. And, of course, all allegations are "unproven" or "unadjudicated" at the outset of a case, which is why the law requires the Court to accept as true Plaintiffs' well pled allegations. In fact, courts routinely find that allegations based on credible short seller reports, and other third-party analysis, are adequate for pleading both falsity and loss causation. Unsurprisingly, Defendants do not cite a ***single*** case holding otherwise.

Defendants also assert that some of their statements are literally true. But the law is clear that a statement can be literally true but misleading where it does not disclose material adverse information, such as data fabrication, conflicts of interest or criminal and civil investigations. As Benjamin Franklin observed: "Half the Truth is often a great Lie." *Poor Richard's Improved, 1758*, Founders Online, National Archives (July 7, 1758), available at https://founders.archives.gov/documents/Franklin/01-07-02-0146. This precept is imbedded in the federal securities laws: there is a duty to disclose "when necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. §240.10b-5(b).

Defendants also claim that the Complaint is "devoid" of allegations demonstrating a "strong inference" of scienter. Mot. at 2. Defendants are wrong. Defendants not only oversaw and authored the research Plaintiffs allege was manipulated, but each spoke at length to the public regarding Cassava's fabricated clinical results. The list goes on. Defendants denied the Citizen Petition's findings before conducting a reasonable investigation. Defendants lied about Wang's involvement with the clinical trial. Defendants attempted to cover-up their fraud by submitting doctored data to scientific journals. Defendants

misrepresented the existence of Cassava's Scientific Advisory Board and then scrubbed information related to it and the Citizen Petition from the internet. Barbier misrepresented the FDA's response to the Citizen Petition. And, although it is not required, Plaintiffs also adequately allege that Defendants were motivated to commit fraud to obtain hundreds of millions of dollars in cash bonuses and to fund Cassava's ability to operate as a going concern. Defendants plainly knew or recklessly disregarded the falsity of their statements.

Defendants' impermissible counter-narrative to these well-pled allegations is completely at odds with reality – and the Complaint. Defendants insist that the Citizen Petition was "false" and that a "majority" of scientific journals had "exonerat[ed]" Burns and Wang after they provided original "underlying images." Mot. at 1, 8-9. But the Complaint confirms that the opposite is true. Burns and Wang did ***not*** submit original data to the journals, but rather provided them with doctored images they attempted to pass off as originals, and numerous journals ***retracted*** and issued ***expressions of concern*** regarding Burns' and Wang's research because they doubted the integrity and reliability of their work. In addition, independent experts in neuroscience and scientific integrity corroborated the Citizen Petition's findings.

Finally, Defendants' argument that the Complaint is an improper puzzle pleading is incorrect. Mot. at 1. A "puzzle pleading" is a complaint that forces the defendants and/or the Court to identify and sort the alleged false statements and corresponding adverse facts in order to match them together and solve the puzzle of interpreting a plaintiff's claims. Here, Plaintiffs have precisely identified each of the alleged false and misleading statements in a dedicated section of the Complaint, with the false and misleading portions of each statement bolded and italicized. The Complaint then matches the corresponding undisclosed adverse facts that caused each statement to be false and misleading. In fact, Defendants can (and do) recognize with relative ease the statements at issue and the reasons why they are false in their Motion.

For these reasons, Defendants' Motion should be denied in its entirety.

II. STATEMENT OF FACTS

A. Cassava and Simufilam

Cassava is a small biotechnology company currently developing simufilam as a treatment for Alzheimer's disease. ¶56. Since commencing operations in 1998, neither Cassava, nor its predecessor, Pain Therapeutics, have produced a single marketable drug. ¶¶74, 76, 82. Cassava is therefore heavily dependent on the success of simufilam, its primary drug candidate. ¶82. In 2018, the Company lost 98% of its value when it failed to gain FDA approval for its then lead product candidate, the opioid Remoxy. ¶¶74, 77. Barbier, nevertheless, still became wealthy, receiving $27 million in compensation. ¶76. Low on cash and prospects, Pain Therapeutics rebranded itself Cassava to focus on Alzheimer's disease, despite having no experience developing Alzheimer's drugs. ¶¶7, 74-75. Though commentators regarded the Company's pivot as Barbier's "latest cash grab" (¶76), Barbier insisted that simufilam was different, pointing to research that Cassava scientists had published in peer-reviewed journals purportedly supporting simufilam's commercial development. ¶¶2, 79, 88, 253-254, 280. Indeed, one of the "[k]ey" elements of Cassava's business strategy was publishing simufilam's "scientific data in peer-reviewed journals." ¶85.

B. Defendants Conceal Rampant Data Manipulation, Anomalies, and Conflicts of Interest in Cassava's Foundational Research

Not long after the rebranding, Cassava reported on May 15, 2020 that its Phase 2b clinical trial of simufilam had failed to demonstrate efficacy in lowering certain biomarkers of Alzheimer's (¶¶8, 90), rendering simufilam's (and Cassava's) future uncertain. ¶91. Months later, however, on September 14, 2020, Cassava reversed course and declared that this initial bioanalysis showed "highly anomalous data" and was therefore "invalid" (¶271), and that pursuant to a new and "valid" "reanalysis" conducted by an "outside lab," the biomarker data now showed a significant improvement. ¶¶9, 268-270, 275-276.

However, despite rejecting the initial Phase 2b bioanalysis as "invalid" due to "anomalous data," Cassava failed to disclose in announcing the reanalysis that several "key" biomarkers (albumin, IL-6 and sTREM2) were themselves ***highly anomalous***, suffering from baseline measurements "far outside expectations" that undermined the reliability of the results. ¶¶227-231, 287(d), 429. Cassava also publicly

misstated several of its "key cognition results" from its Phase 2b Spatial Working Memory test, which did not match the underlying data that Cassava deposited on ClinicalTrials.gov. ¶¶223-226, 274, 287(e).

Defendants further failed to disclose that the reanalysis had not been conducted by an "outside lab," as claimed, but by Professor Hoau-Yan Wang – a Cassava consultant and a member of Cassava's product development team who had a financial interest in the Company and a longstanding (but undisclosed) history of manipulating research. ¶¶57-58, 80, 106-111, 287(f). In addition to holding a financial interest in Cassava, Wang also participated in the Company's bonus plan, an arrangement that Bob Gussin, a member of Cassava's board of directors, described as "not typical," and one that Gussin was "not thrilled with." ¶104. Notably, Barbier considers failures to disclose such conflicts to be "***highly significant***." ¶454. Further, Cassava's failure to disclose Wang's involvement in the reanalysis was ***inconsistent with the Company's prior practice***. ¶456. Wang is currently under investigation by his university, CUNY, for the data manipulation identified in the Citizen Petition. ¶¶28, 368.

On July 26, 2021, Cassava also made a presentation, authored by Burns (Barbier's wife) and Wang, among others, at the AAIC regarding the "final" clinical biomarkers results from the Phase 2b trial. ¶218. In the presentation, Cassava failed to disclose that it had removed a "key" P-tau181 plasma biomarker data point from Figure 4 in the poster (¶¶219, 287(c)), a "***serious and intentional action***" (¶336), in order to conceal that the reduction in P-tau181 in the simufilam treatment groups would not have been considered statistically different from placebo. ¶¶220-221. Had the data point been properly included, the average change-from-baseline would have been just -3%, ***not*** the -17% stated by the Company, "a much less spectacular reduction of plasma P-tau181 levels than claimed." ¶¶222, 315. The presentation also included data that appeared incorrect and "entirely different" from the underlying data obtained via FOIL request. ¶¶232-233, 237-239, 315. Barbier later conceded that data points in Figures 4 and 5 of the AAIC presentation were incorrect. ¶335.

The day after Cassava disclosed the (misleading) results of the Phase 2b reanalysis, Barbier touted

Cassava's pre-clinical research at the September 15, 2020 H.C. Wainwright 22nd Annual Global Investment Conference, remarking on simufilam's results that "***[y]ou don't have to take our word for it. The underlying science is published in a number of peer reviewed journals***." ¶¶280-281. Barbier, however, failed to disclose that many of Cassava's most important pre-clinical papers and related research forming the basis for simufilam's continued development contained extensive data manipulations in the scientific images purporting to capture the results of Cassava's experiments, as well as significant additional anomalies in Cassava's clinical trial outcomes, undermining the reliability and integrity of the Company's results (¶287(a)), including:

- A 2008 *PLoS ONE* paper authored by Burns and Wang, containing manipulated data, including ***spliced*** experiments (*i.e.*, two separate experiments combined as if they were done simultaneously) (¶¶86, 88, 149) and ***duplicated*** results for what are reported as different experiments. ¶¶149, 152, 287(a). As a result, the journal ***retracted*** the paper, and ***four others*** by Burns and/or Wang, based, in part, on the data manipulations raised in the Citizen Petition. ¶154. For each paper, the journal stated that the response provided by the authors "***did not resolve the concerns*** about the integrity and reliability of the reported data." ¶¶39, 423-424.

- The 2012 *Journal of Neuroscience* paper on simufilam authored by Burns and Wang, containing "***duplicated and transposed***" results, including evidence that the published images had been ***intentionally copy-and-pasted*** and otherwise falsified using imaging editing software (¶¶155-176, 287(a)), and experiments that, as described, are ***not possible*** (¶¶373-375) because the antibodies used do not work for the experiments purportedly conducted. ¶¶376-377. As a result, the journal issued an Expression of Concern, a ***highly atypical*** step indicating that the editors had reason to question the ***integrity and accuracy*** of the paper. ¶¶33, 177, 357-360.

- The 2017 *Neurobiology of Aging* paper on simufilam authored by Burns and Wang, containing spliced experiments (¶¶178, 183-184) and images duplicated and manipulated using processing software, a ***deliberate act*** which could not have occurred due to inadvertent error. ¶¶188, 418. In addition, a crucial experiment reflecting simufilam's affinity was also ***not possible***, as the compound used to detect the affinity, C-14, is not suitable for the use described. ¶¶380-384. As a result, after finding an ***extensive list of errors and duplications***, the journal issued an Expression of Concern, indicating that the editors had reason to question the integrity and accuracy of the paper (¶¶189, 414-416), and deferred further judgment until after the ongoing CUNY investigation into Wang concluded. ¶¶416-417. Barbier later conceded that images in the paper were incorrect. ¶334.

- A foundational 2020 *Journal of Prevention of Alzheimer's Disease* ("*JPAD*") paper authored by Wang, Burns, Barbier, and Friedmann publishing the biomarker results from Cassava's Phase 2a trial, in which Cassava "monitored the conduct of the study and data collection." ¶241. As with its Phase 2b results, "key" biomarkers (P-tau181, TNF-α and IL- 1β) contained

"***wildly anomalous baseline measures***" (¶¶245-247) in addition to ***spliced*** images. ¶244. A later statement from the journal never addressed the biomarker abnormalities, nor did it claim that Cassava provided original data to verify whether manipulation had occurred. ¶453, n.16.

- A 2005 *Neuroscience* paper related to simufilam's development authored by Burns and Wang, containing images "***spliced together***" from different experiments (¶¶200-201) and duplicated results (¶¶203-204, 206, 212-213, 215-216), including results ***intentionally duplicated and reused*** to "represent three entirely different proteins, in three entirely different experiments, in three entirely different publications." ¶¶207, 211.

Despite this, throughout the Class Period, Defendants repeatedly lauded the results of the Phase 2b clinical trial reanalysis – including the biomarker, plasma biomarker and Spatial Memory test results specifically; the Phase 2a clinical trial biomarker results; and Cassava's pre-clinical research – without disclosing any of the above information or the numerous other instances of manipulated research in papers authored by Cassava's chief scientists, Burns and Wang. ¶¶287, 295, 305, 308, 311, 315.

C. Cassava's Suspiciously Timed Cash Bonus Plan and Stock Offerings

Shortly before the Company announced the supposedly positive results of the Phase 2b trial reanalysis on September 14, 2020, the Company altered its executive compensation plan to reward Defendants with exorbitant cash bonuses pegged not to meaningful product development milestones, but to short-term, 20-day increases in the Company's stock price. ¶¶2, 9, 91, 98-102. As a result, Cassava executives and directors qualified to receive up to ***$195 million in cash bonuses*** as Cassava's stock price spiked during the Class Period. ¶103. Cassava, which had no product revenue, also took advantage of its skyrocketing stock price in two Class Period stock offerings to raise ***$275 million needed*** to fund simufilam's continued development and fill the Company's bonus pool. ¶¶11, 288, 296, 467-473.

D. The Citizen Petition Begins to Reveal the Truth

After the close of trading on August 24, 2021, reports emerged that the FDA had received a Citizen Petition raising "grave concerns about the quality and integrity of the laboratory-based studies surrounding" simufilam "supporting the claims for its efficacy," including evidence that foundational pre-clinical and clinical studies had been manipulated. ¶¶12-13. The Citizen Petition, which was authored not by typical

short sellers, but by two respected scientists, Drs. David Bredt and Geoffrey Pitt (¶¶112-114, 118-119), attached a 42-page technical report to the petition, as well as numerous subsequent supplemental reports, setting out detailed evidence, including extensive photographic evidence, of data manipulation and anomalies in Cassava's own scientific papers and clinical trial results. ¶¶105-109, 143-251. In response to the Citizen Petition and despite Cassava's strenuous denials, the Company's stock price collapsed, plummeting 39.9% between August 25 and 26, 2021, on heavy trading volume. ¶¶15, 497.

E. Independent Experts Corroborate the Citizen Petition

Prior to the Citizen Petition's publication, Drs. Bredt and Pitt vetted their finding with 10 prominent, independent experts, including neuroscientist and Nobel Laureate Dr. Thomas Südhof. ¶¶122-123. In addition, Drs. Bredt and Pitt hired Dr. Matthew Schrag, an independent neuroscientist at Vanderbilt University, to review Cassava's research. Dr. Schrag identified dozens of duplications and manipulations, many of which were reported in the Citizen Petition. ¶126. When top forensic image analysts and Alzheimer's experts later reviewed Dr. Schrag's findings for the journal *Science*, they "generally agree[d]" with his work, and "many were ***stunned*** by the apparent ***extreme manipulations*** in" the Cassava-linked cases. ¶127.

In addition, Dr. Elisabeth Bik, one of the world's foremost experts in identifying image manipulation in biomedical research (¶¶132-134), independently reviewed the Citizen Petition and "agree[d]" with most of its concerns. ¶¶132, 135-138, 150, 156, 159, 163, 166, 169, 175, 182, 186-187, 205, 208-210. She found that based on the "pattern of irregularities in images in multiple papers," it is "highly likely that there was some manipulation going on." ¶137.[1]

Last, Dr. Mike Rossner, a pioneer in scientific image analysis, reviewed the manipulation

[1] A published study showed that Dr. Bik's determinations are correct ***90% of the time***, and in the remaining 10% of cases, the image quality is too low to allow for a clear answer. ¶133. Defendants misleadingly suggest that Dr. Bik has a financial interested in the Citizen Petition (Mot. at 7) and was "working in concert" with its authors (*id*. at 18). But Dr. Bik expressly disclaimed any such conflicts, and there is no evidence to the contrary. ¶136.

allegations raised by the Citizen Petition at Plaintiffs' request. ¶139. He found that many of the Citizen Petition's data manipulation findings correct (¶¶140, 151, 160, 164, 166, 169, 173, 179, 183, 201, 204, 211-213, 233-235), and that there were additional duplications and manipulations in Cassava's work, as well. ¶¶152, 161, 164, 170-171, 174, 184, 214.

F. Cassava's Misleading Response to the Citizen Petition

On August 25, 2021, the morning after the Citizen Petition's release, Cassava made a public statement before the market opened denying the petition's findings and labeling various statements from the Citizen Petition as "fiction" before setting out the purported "facts," according to Cassava. ¶¶14, 316-317. But, as Dr. Bik found, "some of these facts were clearly, in my opinion, fiction," and "not written by a person who had any knowledge about molecular biology or about blots in general." ¶322. Among the purported "facts," Cassava claimed that its "plasma p-tau data from Alzheimer's patients was generated by [Quanterix], an independent company, and presented at the recent Alzheimer's Association International Conference[]," and that the missing p-tau biomarker data from the AAIC poster had "increased by 38%, not 235%[]." ¶¶316-317.

But the missing plasma P-tau181 biomarker data from the presentation showed an increase of 150%, ***not*** 38%. ¶¶220, 319, 329. And, two days later, on August 27, Quanterix issued its own press release making clear that it "did ***not*** interpret the test results ***or*** prepare the data charts presented by Cassava" in the AAIC presentation. ¶¶16, 323. On this news, the Company's share price fell 17.66%, on unusually heavy trading volume. ¶¶17, 499.

G. Defendants' Attempts to Cover-Up Their Fraud

1. Doctored Images Submitted to the *Journal of Neuroscience*

On November 4, 2021, Cassava issued a press release stating that the *Journal of Neuroscience* had "requested ***raw data*** for the article, including ***images of original, uncropped Western blots***" and ***"[h]aving received that data*** and completed its review, the *Journal of Neuroscience* states: 'No evidence of data

manipulation was found for Western blot data.'" ¶¶338-339, 342. Cassava did not disclose, however, that the article's authors, Burns and Wang, ***never provided*** the "raw data" and "original" images, but had rather submitted ***doctored data*** in an attempt to exonerate themselves. ¶¶343, 346-347, 355. Burns even emailed another journal that "***we*** have already responded to JNS [*Journal of Neuroscience*] with ***original blots (exonerating claims of fraud***). . . ." ¶356. But when the journal published an "Errata" containing the purported "original" data, it was apparent that ***no original data had been submitted***. ¶¶24, 344.

The Errata did not address numerous data manipulations, and the so-called "originals" did not contain the required indicia of original images, such as the edges of the x-ray film from which the images were obtained or the molecular weight markers present in original images. ¶347. Thus, the purported "original, uncropped" images were not originals at all, but rather composites of cropped images (¶¶347-348, 354), which themselves contained alternations and did not match the images first published in the original article. ¶¶350-353. Emails between Wang and the journal confirmed that Wang could not find "the blots" and merely provided a "powerpoint," not the original, "raw data." ¶355.

After Dr. Bik publicly raised concerns regarding the authenticity of the purported "original" data Burns and Wang had supplied, the *Journal of Neuroscience* ***changed*** its statement into an ***Expression of Concern***, a highly atypical step indicating the journal had reason to question the integrity of the paper, and acknowledged the problematic "original" data, deferring further judgment until CUNY finished its ongoing investigation. ¶¶33, 357.

2. Doctored Images Submitted to *Neuroscience*

On December 21, 2021, Cassava issued a press release publishing a statement from the journal *Neuroscience* that, "[i]n response to allegations of data manipulation . . ., the journal ***asked the authors for images of the original, uncropped Western blots*** from this study" and that after review of the "***original material***, *Neuroscience* found no evidence of manipulation." ¶386-387. Burns and Wang, however, ***did not*** provide the original, uncropped Western blots to the journal, as Defendants represented to the public in the

Company's press release. ¶389.

Once again, after the journal made the purported "original" blots Burns and Wang supplied publicly available, Dr. Bik and others highlighted that, "as with the *J Neuroscience* correction," the "original" blots "should actually be X-ray films, as stated in the paper. Instead, the authors provided images without blot edges, labels, or markers." ¶¶390-393. All the purported "original" images were therefore cropped and not the original source data, as claimed in Cassava's press release. ¶396. In addition, the purported "original" images contained duplicate blots copied and pasted onto falsified backgrounds (¶¶390-393, 402-403), and indicia that Burns and Wang digitally deleted aspects of the images before submitting them to the journal. ¶¶397-398, 400. Email correspondence between Burns and *Neuroscience* further suggests that original data was never provided, as Burns claimed that the hard drive containing the data purportedly "melted years ago." ¶406.[2]

3. Cassava Scrubs Negative Information from the Internet

In its Class Period SEC filings, Cassava claimed that the Company was supported by a scientific advisory board comprised of "[l]eading experts," including Barbara Sahakian, Steven Arnold, and three others. ¶480. But when Sahakian disclosed in October 2021 that she had "not worked with Cassava for years," the Company deleted its Scientific Advisory Board link from its website. ¶481. Later, Arnold revealed that Cassava, in fact, had no "formal advisory board meetings" since Cassava changed its name from Pain Therapeutics in 2019. ¶482. Additionally, in violation of Wikipedia policies and without disclosing their conflict of interest, an IP address ***originating from Cassava's headquarters*** edited Wikipedia pages for simufilam and Burns to remove mentions of Burns' marriage to Barbier and dismiss alleged research misconduct. ¶484.

H. The Resulting Government Investigations

[2] In addition, three other journals ***retracted*** five additional papers authored by Wang after he failed to address data manipulation allegations, even though purported "original" or "raw" data was supposedly provided, which also showed signs of manipulation. ¶¶37, 39, 42, 409-410, 423-424.

On November 15, 2021, Cassava disclosed in its Form 10-Q that "[c]ertain" unnamed government agencies "have asked us to provide them with corporate information and documents." ¶¶26, 363. Defendants did not disclose, however, that Cassava was the subject of the investigations, including civil and criminal investigations by the SEC, DOJ, and NIH, which specifically pertained to the allegations of manipulated research results raised in the Citizen Petition. ¶¶28, 30, 365. When a November 17, 2021 *Wall Street Journal* article revealed the SEC and NIH investigations and their scope two days later, Cassava's stock price dropped 23.7%. ¶¶28, 30, 501. Then, on July 27, 2022, when Reuters published a story disclosing the DOJ's criminal investigation into the Company's manipulated research results (¶435), Cassava's stock price fell 14%. ¶¶44-45, 505.

I. The FDA's Response to the Citizen Petition

On February 10, 2022, the FDA responded to the Citizen Petition "acknowledge[ing] the importance of the issues" raised but denying the petition "***solely***" on technical grounds, finding that the petition's request for an FDA investigation was not appropriate relief for a citizen petition. The FDA, however, took special care to note that its decision "***does not represent a decision by the Agency to take or refrain from taking any action relating to the subject matter of your Petitions***." ¶411.

Yet, in a press release Cassava issued that same day, Barbier suggested that Cassava had been cleared of wrongdoing by the FDA (¶412) and later publicly stated that "the FDA says there is no evidence" of fraud (Mot., Ex. 8 at 4). Following Barbier's statement, a stock analyst issued a report rebutting Barbier's characterization, writing that "[w]hile the FDA did deny the Citizen's Petition, it was ***not*** because the FDA did not find evidence of fraud based on the evidence presented." ¶413.

J. *The New York Times's* Cassava Exposé

On April 18, 2022, *The New York Times* published a wide-ranging exposé on Cassava, in which reporters interviewed nine "prominent experts for comment about the scientific underpinnings of Cassava's trials." According to the newspaper, "[a]ll said they did not trust the company's methods, results or even the

premise underlying the drug's supposed effectiveness" (¶¶40, 425) and knew of no independent studies that would explain the Company's results. ¶428. In the article, Dr. Bik stated that "[b]ased on the pattern of irregularities in images in multiple papers, she believes 'it is highly likely that there was some manipulation going on.'" *Id*. On this news, Cassava's stock price fell 11.3% on April 19, 2022. ¶503

III. LEGAL STANDARDS

Motions to dismiss securities actions are "'viewed with disfavor and are rarely granted.'" *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009).[3] On a Rule 12(b)(6) motion to dismiss a §10(b) action, courts must "accept all factual allegations in the complaint as true" and "draw all reasonable inferences in the plaintiff's favor." *Id*. Courts do not resolve disputed issues of fact. *See Smith v. Reg'l Transit Auth.*, 756 F.3d 340, 347 (5th Cir. 2014). Accordingly, "a dismissal pursuant to Rule 12(b)(6) is difficult to obtain since such a claim revolves around fact-specific inquiries." *Brody v. Zix Corp.*, 2006 WL 2739352, at *2 (N.D. Tex. Sept. 26, 2006). To withstand a motion to dismiss, the Complaint simply need allege "'the who, what, when, where, and how'" of the fraud. *Benchmark Elecs., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. 2003).

IV. ARGUMENT

A. Plaintiffs Adequately Allege False and Misleading Statements

To sufficiently allege falsity, Plaintiffs need only "'specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent.'" *Barrie v. Intervoice-Brite, Inc.*, 397 F.3d 249, 256 (5th Cir. 2005). The Complaint readily meets this standard.[4]

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[3] All citations are omitted and emphasis is added unless otherwise noted.

[4] Contrary to Defendants' contention, the Complaint is not a "puzzle" (Mot. at 12), Plaintiffs' recitation of the undisclosed facts that rendered certain Defendants' statements false and misleading does not make the Complaint a "'puzzle pleading.'" *Rougier v. Applied Optoelectronics, Inc.*, 2019 WL 6111516, at *8 (S.D. Tex. Mar. 27, 2019). And Defendants' claims are further belied by their targeted arguments challenging the sufficiency of the very statements they claim are not specified. *See* Mot. at 13-21. Defendants' cases are

1. Misstatements Concerning Cassava's Research

Defendants repeatedly touted Cassava's pre-clinical papers and clinical trial results in public statements without disclosing that the research was rife with manipulated data and significant anomalies undermining the integrity and reliability of their results. In doing so, they violated the basic disclosure principle that, once corporate executives speak on a subject, they have "a duty to ***tell the whole truth***, and disclose 'material, firm-specific adverse facts.'" *In re ArthroCare Corp. Sec. Litig.*, 726 F. Supp. 2d 696, 716 (W.D. Tex. 2010); *Bach v. Amedisys, Inc.*, 2016 WL 4443177, at *9 (M.D. La. Aug. 19, 2016) (when a corporation make a voluntary disclosure "'there is a duty to make it complete and accurate'").

a. Misstatements Concerning Data Manipulation

Defendants' statements touting specific "key" and "foundational" pre-clinical research and their Phase 2a and 2b clinical trial results concealed that they contained rampant and intentional splicing, duplication and other forms of data manipulation and falsification, as well as experiments that could not have been conducted using the methods described. This concealed information rendered those statements misleading. §II.B.; ¶¶287, 295, 305, 308, 311, 315. *See Schueneman v. Arena Pharms., Inc.*, 840 F. 3d 698, 705-06, 708 (9th Cir. 2016) ("'[O]nce defendants cho[o]se to tout' [allegedly positive information concerning preclinical studies] 'they [are] bound to do so in a manner that wouldn't mislead investors,'" as to "potentially negative information within their possession."); *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014) (finding statements "lauding" conclusions from studies of a company's flagship drug candidate that were based on a "statistically unsound analyses of empirically defective trials" materially misleading).

In response, Defendants raise a host of meritless arguments. *First*, Defendants claim (wrongly) that

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thus inapt. In *In re Alamosa Holdings, Inc. Sec. Litig.*, 382 F. Supp. 2d 832, 857 (N.D. Tex. 2005), unlike here, the plaintiffs did not even "attempt to explain why [the] statements are false and misleading" and did not "specify which of the various statements . . . are false or misleading." And in *Primo v. Pac. Biosciences of Cal., Inc.*, 940 F. Supp. 2d 1105, 1112 (N.D. Cal. 2013), unlike here, the plaintiffs "present[ed] [lists] of alleged omissions or misstatements but fail[ed] to connect [them] to any particular statements."

falsity cannot, as a matter of law, be established by the Citizen Petition because the data manipulation allegations are based on "uncharged, unadjudicated, and unsubstantiated accusations." Mot. at 14, 16.[5] But courts have rejected this contention and routinely accept allegations based on so-called "short-seller report[s]." *See In re Eros Int'l PLC Sec. Litig.*, 2021 WL 1560728, at *9 (D.N.J. Apr. 20, 2021) ("the Court credits Plaintiffs' allegations that emanate from the Hindenburg article as true"); *McIntire v. China MediaExpress Holdings, Inc.*, 927 F. Supp. 2d 105, 123-24 (S.D.N.Y. 2013) (rejecting argument that "'unsubstantiated and uncorroborated allegations of short sellers' do[] not satisfy the pleading requirements of Rule 9(b)"). Indeed, "[t]he truth of the [Citizen Petition] is "'a factual dispute not appropriate for resolution at this stage.'"" *Id*. at 124. *See In re Cobalt Int'l Energy, Inc.*, 2016 WL 215476, at *4 (S.D. Tex. Jan. 19, 2016) ("The content of the articles is properly alleged and the accuracy of the articles is not a proper subject for a motion to dismiss."). Accordingly, "[i]t is permissible for Plaintiffs to rely on a short seller report . . . to allege falsity at the pleading stage." *Snellink v. Gulf Res., Inc.*, 870 F. Supp. 2d 930, 939 (C.D. Cal. 2012). Notably, if Defendants' position were adopted, a plaintiff would be unable to plead a securities fraud claim unless the conduct underlying the claim had been, at a minimum, criminally charged. This, of course, is not the law. *See* §IV.C., *infra*.

Second, Defendants argue that the Citizen Petition is not based on "facts," but is rather comprised of "speculative" "opinions" from commentators without "first-hand knowledge." Mot. at 14-15. Defendants are wrong. The detailed facts and supporting documentation (including photographic evidence) pled in the Complaint show specific and widespread instances of data manipulation based on first-hand analysis of ***Cassava's own data*** (§II.B.). *See In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d 714, 731 (N.D. Cal. 2022) (rejecting argument that analyst report offering opinions is devoid of "'true

[5] Defendants' claim also appears untrue, as the NIH ***has*** undertaken some level of adjudication against Cassava. As the Company recently admitted in a lawsuit against Drs. Bredt and Pitt, after the Citizen Petition came to light, "Cassava could no longer obtain funding from the NIH." *Cassava Sciences, Inc. v. Bredt, et al.*, 1:22-cv-09409-GHW (S.D.N.Y.), ECF 1, at 171.

facts'" where it is "littered with factual assertions that purport to show that QuantumScape's own factual assertions are incorrect").[6]

In addition to the numerous independent experts that have corroborated the allegations in the Citizen Petition, its reliability is also strengthened by the severe drop in Cassava's stock price when the petition was revealed. §II.D.-E. *See Bond v. Clover Health Invs., Corp.*, 587 F. Supp. 3d 641, 668 (M.D. Tenn. 2022) (accepting allegations based on a short seller report where "[i]t appear[ed] that the market itself agreed, reacting negatively . . . in a way that would not make sense if the Report had lacked credibility in the eyes of reasonable, knowledgeable investors").[7]

Third, Defendants' suggestion that, in order to state a claim, Plaintiffs must somehow obtain Cassava's original data and definitively prove, at the pleading stage and without discovery, that the Company manipulated its pre-clinical and clinical research (Mot. at 14-18) is meritless. "[T]he particularity rules should not be interpreted to require the pleading of facts which, because of the lack of discovery, are in defendants' exclusive possession." *In re Fleming Cos. Inc. Sec. & Derivative Litig.*, 2004 WL 5278716, at *6 (E.D. Tex. June 16, 2004). Nor is there a requirement that the Complaint include allegations from

[6] Defendants' citation to *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278 (5th Cir. 2006) is inapt. That case concerns whether a court may consider an expert declaration attached to a complaint, and it affirmed the district court's decision to consider factual, as opposed to conclusory, portions of the expert's declaration. *Id*. at 286. Plaintiffs here, by contrast, have not attached any expert declaration to the Complaint, and Plaintiffs' well pled factual allegations are not conclusory. *See In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 821 (C.D. Cal. 2011) (noting the "better approach" of "include[ing] the expert's nonconclusory assertions within specific paragraphs in the complaint"); *also Pub. Emps. Ret. Sys. of Miss., P.R. Tchrs. Ret. Sys. v. Amedisys*, 769 F.3d 313, 323, n.3 (5th Cir. 2014) (noting use of declaration of outside expert to support plaintiff's allegations); *Blanchard-Daigle v. Geers*, 802 F. App'x 113, 115-16 (5th Cir. 2020) (considering "'nonconclusory, factual portions'" of an expert declaration attached to a complaint on a motion to dismiss).

[7] Defendants' cases are inapposite. In *Sgarlata v. PayPal Holdings, Inc.*, 409 F. Supp. 3d 846, 860 (N.D. Cal. 2019), unlike here, the expert did ***not*** review documents available to the defendants at the time of their statements that demonstrated the inconsistencies in those statements. *Aff'd sub nom. Eckert v. PayPal Holdings, Inc.*, 831 F. App'x 366 (9th Cir. 2020). Here, numerous individuals reviewed Cassava's data, which was available prior to and at the time of Defendants' statements. *Applestein v. Medivation, Inc.*, 561 F. App'x 598, 600 (9th Cir. 2014) and *In re Molycorp, Inc. Sec. Litig.*, 2015 WL 1540523, at *16 (D. Colo. Mar. 31, 2015) are distinguished for the same reasons.

former Cassava employees with "first hand" knowledge of the data manipulations, especially given the Company's small size. Mot. at 14. *See Tomaszewski v. Trevena, Inc.*, 482 F. Supp. 3d 317, 334 (E.D. Pa. 2020) ("[T]here is no requirement that plaintiffs in a securities fraud action support their allegations with information attributed to confidential witnesses."). The PSLRA "'was not enacted to raise the pleading burdens under Rule 9(b) and section 78u-4(b)(1) to such a level that facially valid claims . . . must be routinely dismissed on Rule 9(b) and 12(b)(6) motions.'" *Edwards v. McDermott Int'l, Inc.*, 2021 WL 1421609, at *8 (S.D. Tex. Apr. 13, 2021).[8]

Fourth, Defendants claim that Plaintiffs' allegations must fail because there is no duty to disclose "uncharged criminal behavior." Mot. at 13-14. But Plaintiffs do not allege Defendants had an independent duty to disclose uncharged criminal behavior. Instead, Plaintiffs allege Defendants made false and misleading statements, regardless of whether they were in violation of some other law, by failing to make "full and truthful" disclosures once they chose to speak publicly about the topic. *See In re El Paso Elec. Co. Sec. Litig.*, 2004 WL 377555, at *5-*6 (W.D. Tex. Feb. 23, 2004) (rejecting argument that company "did not have a duty under securities laws to publicly accuse itself of wrongdoing" because "irrespective of the FERC's rules or regulations," where the company had "'disclosed' the existence of [a services agreement with Enron], they were required to make a full and truthful disclosure of all the aspects of that agreement"); *Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 584 (S.D.N.Y. 2016) ("But the question here is not whether Och-Ziff had an independent duty to announce the SEC-DOJ Investigation; it is whether, in light of that Investigation, the statements Och-Ziff chose to make were materially misleading.").[9]

[8] Defendants repeatedly claim that Plaintiffs must show "authoritative evidence" that "wrongdoing" occurred (Mot. at 14, 17), citing *Parker v. Hyperdynamics Corp.*, 126 F. Supp. 3d 830, 843 (S.D. Tex. 2015). But that case does not establish a new standard for pleading false and misleading statements, or even explain what "authoritative evidence" is. Yet, Plaintiffs do plead specific evidence of manipulations.

[9] Additionally, in Defendants' cases, unlike here, the alleged falsity was based on allegations that the defendants had violated criminal law. *See Parker*, 126 F. Supp. at 843 ("the disclosures were false or

Fifth, Defendants broadly mischaracterize Plaintiffs' allegations, asserting as "facts" statements taken from the Complaint's "***False and Misleading Statements" section***.[10] But most boldly, Defendants claim that the "majority of the journals inquires have resulted in exoneration for Wang and/or Burns." Mot. at 9. That is ***patently false***:

> (i) *PLoS One* ***retracted*** five of their articles because of concerns with the reliability and integrity of the data (¶¶39, 423-424);
>
> (ii) *Molecular Neurodegeneration* ***retracted*** Wang's paper due to irregularities found in his work and because the "original" data Wang provided the journal as part of the investigation also had signs of image manipulation (¶¶37, 408-410);
>
> (iii) *Alzheimer's Research & Therapy* ***retracted*** Wang's paper because it "no longer ha[d] confidence in the integrity of the data" (¶¶42, 433-434);
>
> (iv) *Journal of Neuroscience* issued an ***Expression of Concern***, indicating it had reason to question the integrity of the paper, after Burns and Wang submitted doctored data to the journal, and deferred further action until the CUNY investigation concludes (¶¶338-362);
>
> (v) *Neurobiology of Aging*, after finding an extensive list of errors in the paper, issued an ***Expression of Concern***, indicating the journal had reason to question the integrity of the paper, and ***reserved*** final judgment until the CUNY investigation concludes (¶¶38, 177, 414-418);
>
> (vi) Plaintiffs allege Burns and Wang provided ***doctored data*** to *Neuroscience* to obtain an exculpatory statement under false pretenses (¶¶386-407); and

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misleading by omission, because [FCPA] violations occurred"); *In re KBR, Inc. Sec. Litig.*, 2018 WL 4208681, at *3 (S.D. Tex. Aug. 31, 2018) (falsity based on defendants being "engaged in bribery"); *In re Key Energy Servs., Inc. Sec. Litig.*, 166 F. Supp. 3d 822, 863 (S.D. Tex. 2016) (dependent on FCPA violations). Moreover, there were no particularized allegations that a violation of the law occurred. Here, Plaintiffs pled particularized allegations that data manipulation occurred.

[10] Defendants' improper alternative "facts" were never pled as such, but were rather taken from the ***false statement*** section of the Complaint. Moreover, they are plainly disputed. For example, Defendants claim that: (i) the initial Phase 2b results "did not demonstrate poor results" (Mot. at 4, citing ¶304), when, in fact, the trial failed to reach its primary endpoints (¶¶90-91); (ii) the initial Phase 2b analysis was "apparently" incorrect due to error (Mot. at 4-5, citing ¶304), but Cassava never identified what purported "error" had been made (¶¶94-96); (iii) the Phase 2b reanalysis data was "promising" and contained no "pattern of anomalies in the placebo data" (Mot. at 5, citing ¶304), when, in fact, "key" biomarker data in the Phase 2b reanalysis was highly anomalous (¶¶227-231); (iv) "key" plasma biomarker data in the Phase 2b trial "corroborated" biomarker data in the Phase 2b reanalysis (Mot. at 5, citing ¶317), when, in fact, Defendants manipulated the Phase 2b plasma biomarker data in order to falsely represent that P-tau181 (an indicator of Alzheimer's disease) levels had been "significantly" lowered when they had not; and (v) the Phase 2b biomarker results were "supported" by non-final interim an open label study (Mot. at 5, ¶289), when open label study results are not reliable. ¶¶10, 115.

(vii) *Journal of Prevention of Alzheimer's Disease's* statement did ***not*** address the abnormalities in the biomarker data or state that any original data had been provided to the journal. ¶453 n.16.

Defendants' improper (and logically unsound) arguments are "insufficient to support a motion to dismiss." *Holzwasser v. Staktek Holdings, Inc.*, 2006 WL 897746, at *4 (W.D. Tex. Mar. 30, 2006).

b. Misstatements Concerning Anomalous and Incorrect Data in Cassava's Phase 2b and 2a Clinical Trials

Defendants' statements acclaiming "key" and purportedly "valid" biomarker results from simufilam's Phase 2a trial and 2b reanalysis are misleading. §II.B; ¶¶287(c)-(e), 295, 305, 308, 311. Defendants concealed that both simulfilam's Phase 2a trial and 2b reanalysis suffered from highly anomalous baseline measurements undermining the reliability and validity of the results, and misstated the results of the Spatial Memory test. *Id*. Indeed, Defendants said nothing about the anomalous results, despite having just declared Cassava's original Phase 2b trial results ***invalid*** because they were themselves ***anomalous***. *See* §II.B. But Defendants cannot tout the good while withholding the bad.[11]

In addition, Defendants' statements concerning the P-tau181 plasma biomarker results from the Company's Phase 2b trial were false and misleading for multiple reasons, including because Cassava intentionally removed unfavorable data to conceal that the change in p-tau plasma in patients taking simufilam was not statistically different than the placebo group. §II.B.; ¶¶219-222, 315. *See In re Forest Lab'ys Sec. Litig.*, 2006 WL 5616712, at *7 (S.D.N.Y. July 21, 2006) ("publishing clinical data favorable

[11] *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F. 3d 988, 1010, 1015 (9th Cir. 2018) ("once Orexigen chose to tout the apparently positive 25 percent interim results, Orexigen had the obligation also to disclose that they were likely unreliable" and to disclose information "that diminished the weight of those results"); *Schueneman*, 840 F.3d at 705-06 ("'[O]nce defendants cho[o]se to tout' positive information to the market, 'they [are] bound to do so in a manner that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information."); *Voulgaris v. Array Biopharma Inc.*, 2020 WL 8367829, at *15, *22 (D. Colo. Nov. 24, 2020) (misleading for company to provide "only the positive results to the public while holding back the negative results"); *City of Birmingham Relief & Ret. Sys. v. Acadia Pharms., Inc.*, 2022 WL 4491093, at *10 (S.D. Cal. Sept. 27, 2022) ("failure to disclose that the studies were not properly designed and that [a study] had disappointing subgroup data rendered Defendants' positive statements regarding the results of the studies materially misleading").

to [a drug] while concealing unfavorable data" is misleading under §10(b)). Accordingly, Defendants' claims that there had been a "significant" 17% reduction in P-tau181 plasma, when the true change was a non-significant 3% reduction, were also false and misleading. §II.B.; ¶¶219-222, 315.

2. Misstatements Concerning Conflicts of Interest

Plaintiffs have adequately pled that Defendants' statements that Cassava's Phase 2b reanalysis was conducted by an "outside" lab were false and misleading. Defendants failed to disclose that the reanalysis was conducted by Wang, a paid Company consultant and a member of Cassava's "in-house" product development team with a history of data manipulation. §II.B; ¶¶57-58, 80, 104, 287(f). Notably, Wang had an ownership interest in Cassava and a direct interest in the outcome of the Phase 2b reanalysis given his participation in Cassava's bonus plan. *Id*. *See The MJK Fam. LLC v. Corp. Eagle Mgmt. Servs., Inc.*, 2009 WL 4506418, at *8-*9 (E.D. Mich. Nov. 30, 2009) (failure to disclose known conflict of interest misleading); *also Zweig v. Hearst Corp.*, 594 F.2d 1261, 1266 (9th Cir. 1979) (duty to disclose conflict of interest in news report arose because reasonable investors might have discounted validity of projections if they knew that author of the report stood to profit if investors heeded the analyst's advice), *abrogated sub nom. Hollinger v. Titan Cap. Corp.*, 914 F.2d 1564 (9th Cir. 1990).

Defendants' arguments that their statements regarding the "outside" lab cannot be false or misleading because they are "indisputably true" (Mot. at 19) lack merit. "[T]he disclosure required by the securities laws is measured not by literal truth, but by the ability of the statements to accurately inform rather than mislead prospective buyers." *Lormand*, 565 F.3d at 248-49. Thus, "statements that are demonstrably true or expressions of opinion are nevertheless actionable if the statements omit additional material information whose absence makes the fact or opinion misleading to a reasonable person reading the statement fairly and in context." *City of Birmingham.*, 2022 WL 4491093, at *10.[12]

[12] Though Defendants do not dispute the materiality of any alleged misstatement or omission, Barbier himself has publicly stated that the disclosure of such conflicts "matter." ¶454; *see* §II.B. Moreover, whether Defendants' disclosure was adequate "is a mixed question of fact and law and, therefore, is a

3. Misstatements in Cassava's Response to the Citizen Petition

In a desperate effort to disparage the Citizen Petition's findings, Defendants resorted to simply making up "facts." ¶316. But once an executive choses to respond to a short seller report, they are "'required to speak the full truth and accurately inform, rather than mislead, investors.'" *Bach*, 2016 WL 4443177, at *13. First, in response to the finding that Cassava's P-tau181 plasma biomarker data in the July 26, 2020 AAIC's presentation had been manipulated, Cassava claimed that the data had been "generated by [Quanterix], an independent company, and presented at the [AAIC]" in an attempt to misleadingly suggest that the data presented was validated by an independent lab and therefore correct. §II.F.; ¶¶14, 316-319, 323-324. But Quanterix found the statement to be so misleading that it issued its own release two days later to correct Cassava, stating that Quanterix "did ***not*** interpret the test results ***or prepare the data***" Cassava presented at the AAIC. §II.F.; ¶¶323-324. When Quanterix set the record straight, Cassava's stock price plummeted 17.66%. §II.F.; ¶¶327, 449. Defendants' statement about Quanterix was plainly misleading, and Defendants fact-based arguments to the contrary are inappropriate. *See Isquith*, 847 F.2d at 208.

Second, Cassava claimed that the plasma P-tau181 data point missing from the AAIC poster had only "increased by 38%." §II.F; ¶317. But, in fact, the missing data point reflected a ***150% increase***. §§II.B; II.F; ¶¶220, 319, 329. As a result, and contrary to Defendants' claims, the simufilam treatment group did ***not*** show a "significant" ability to lower the P-tau l81 plasma Alzheimer's biomarker. *Id*.

4. Misstatements Concerning Government Investigations

Defendants made misleading statements about the government investigations. Cassava disclosed only that "[c]ertain" unnamed government agencies "asked" the Company to "provide them with corporate information and documents" (§II.H) and that it "'cannot predict the outcome or impact of any [of] these ongoing matters.'" Mot. at 20. But Cassava concealed that: (i) it was the subject of civil and criminal

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question for a jury" (*Isquith for & on Behalf of Isquith v. Middle S. Utils., Inc.*, 847 F.2d 186, 208 (5th Cir. 1988)), not a question for a Rule 12(b)(6) motion to dismiss.

investigations by the SEC, DOJ, and NIH into the allegations of manipulated research results; and (ii) that the investigations ***were*** having an impact; the Company could no longer obtain important funding from the NIH. *See id*.; Fn. 4, *supra*. Cassava therefore misleadingly failed to disclose the "existence of significant additional legal and regulatory risks . . . that go beyond the limited risks disclosed" and that "Defendants were already being adversely affected by these risks." *Franchi v. SmileDirectClub, Inc.*, 2022 WL 4594575, at *16-*17 (M.D. Tenn. Sept. 30, 2022). In other words, "[Cassava] opted to speak on the subject of investigations, but 'did not speak in an accurate and complete manner.'" *Menaldi*, 164 F. Supp. 3d at 583-84 (statements obfuscating the "existence and scope" of a SEC-DOJ investigation misleading). *See also Bond*, 587 F. Supp. 3d at 672, 680 (undisclosed DOJ investigation was a "significant risk" rendering "statements about routine inquiries" misleading).

Defendants' assertion that the disclosure was literally true (Mot. at 19-21) is no defense. "[T]he 'veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers.'" *In re BioScrip, Inc. Sec. Litig.*, 95 F. Supp. 3d 711, 727 (S.D.N.Y. 2015); *see Wilson v. Merrill Lynch & Co., Inc.*, 671 F.3d 120, 130 (2d Cir. 2011) (quoting *SEC v. Gabelli*, 653 F.3d 49, 57 (2d Cir.2011), *rev'd*, 568 U.S. 442 (2013)) ("The law is well settled . . . that so-called "half-truths" – literally true statements that create a materially misleading impression – will support claims for securities fraud.'"). Defendants, moreover, do not address why, if their disclosure was both true and not misleading, Cassava's stock price collapsed 23.7% and another 14% when the truth regarding the scope of the investigations was revealed. *See* §II.H.[13]

B. Plaintiffs Adequately Allege Scienter

A party satisfies the scienter pleading requirement by alleging either an "intent to deceive" or

[13] Defendants' cases are distinguishable. Mot. at 19-20. None concerns the circumstances present here: (i) a failure to disclose the extent and scope of multiple civil and criminal investigations; and (ii) a misrepresentation that those investigations were ***already*** having a negative effect on the Company's business. *See In re Inv. Tech. Grp., Inc. Sec. Litig.*, 251 F. Supp. 3d 596, 615 (S.D.N.Y. 2017); *In re KBR*, 2018 WL 4208681, at *8; *In re Lions Gate Ent. Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 15 (S.D.N.Y. 2016).

"severe recklessness." *Spitzberg v. Hous. Am. Energy Corp.*, 758 F.3d 676, 684 (5th Cir. 2014). An inference of scienter need not be "irrefutable, *i.e.*, of the 'smoking-gun' genre, or even 'the most plausible of competing inferences.'" *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007). In assessing scienter, the "inquiry is whether all of the facts alleged, ***taken collectively***, give rise to a strong plausible inference of scienter, ***not*** whether any individual allegation, scrutinized in isolation, meets that standard." *Lormand*, 565 F.3d at 251. A complaint cannot be dismissed if "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Stated differently, "'a tie favors the plaintiff.'" *Spitzberg*, 758 F.3d at 686. Taken together, Plaintiffs' allegations raise a strong inference of scienter, and, contrary to Defendants' claims, do not rest on generalizations based on Defendants' positions in the Company. Mot. at 28. Instead, Plaintiffs raise specific allegations regarding: (i) what each Defendant knew or recklessly disregarded at the time of their misstatements; (ii) Defendants' motive to commit fraud; and (iii) other behavior exhibiting fraudulent intent, including attempts to cover-up their misdeeds.

1. Defendants Knew or Recklessly Disregarded the Problems with the Pre-Clinical Research and Clinical Trials at Issue

"'The Fifth Circuit has held that material misstatements as to a company's most significant asset can give rise to a strong inference that those misstatements were made with knowledge of their falsity or severe recklessness in not knowing that they were false.'" *Rougier*, 2019 WL 6111516, at *12; *In re OCA, Inc. Sec. & Derivative Litig.*, 2006 WL 3747560, at *18 (E.D. La. Dec. 14, 2006) (same); *Holzwasser*, 2006 WL 897746, at *4 (misstatements that "pertained to [company's] core business" supported scienter).

Plaintiffs allege that Cassava's executives in charge of developing the Company's primary drug candidate – Defendants Barbier, Burns, and Friedmann – knew or recklessly disregarded the adverse information in simufilam's Phase 2b and Phase 2a trial results and pre-clinical research. §II.B.; ¶¶438-445. *See In re Amylin Pharms., Inc., Sec. Litig.*, 2002 WL 31520051, at *8 (S.D. Cal. Oct. 10, 2002) ("Because SYMLIN was Amylin's primary drug candidate and Amylin is a small biotech company, defendants Cook

and Greene are properly charged with knowledge of the misstatements regarding severe hypoglycemia.") (citing *Nathenson v. Zonagen*, 267 F.3d 400, 425-26 (5th Cir. 2001) (finding strong evidence of scienter with respect to company officer where Zonagen was a small, essentially one-product company, the company's prospects were substantially dependent on that product and the alleged misstatements concerned that product)); *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 700 (5th Cir. 2005) ("It is reasonable to assume, given the importance of these deals to the company, that IPaxess would have familiarized itself with the financial condition of Lynxus/AGNI and would have discovered details about their poor financial condition . . . .").

As members of Cassava's simufilam development team, and since Cassava had few employees, Defendants Barbier, Burns, and Friedmann ***oversaw and even authored*** the pre-clinical research and clinical trial results alleged to be false and misleading. ¶¶59, 61, 64, 441, 443, 445. Defendants Barbier, Burns, and Friedmann all authored Cassava's 2020 *JPAD* paper reporting the results of the Company's Phase 2a trial in simufilam, which are alleged to be false and misleading. ¶¶241-247, 441. And Burns not only explicitly "monitored" the pre-clinical experiments and "oversaw" Cassava's clinical trials (¶442; *see also* ¶¶461-462), she co-authored the pre-clinical and clinical research papers alleged to have been manipulated (¶¶61, 149, 155, 178, 200, 207, 216) and the Cassava presentations containing manipulated data alleged to be false and misleading, such as the November 7, 2020 CTAD presentation (¶¶223-226, 232, 442) and the July 26, 2021, AAIC presentation. ¶¶218-222, 232-240, 442.[14] Accordingly, these defendants knew that data had been manipulated because they prepared and reviewed the very reports containing manipulated data. *See Frater*, 996 F. Supp. 2d at 349-50 (finding scienter where defendants "are all alleged to have been in position to know of departures from protocol, statistical manipulation, and the like"). Indeed, "***[t]he only compelling, possible inference*** is that [Defendants] were either aware of the

[14] Like Defendants' arguments that "unadjudicated" allegations cannot support falsity, their claims that they cannot support an inference of scienter (Mot. at 23) fail for the same reasons. §IV.A.1.

truth and intentionally misled investors (or remained silent while investors were being misled), or were willfully blind and severely reckless in ignoring the truth." *ArthroCare*, 726 F. Supp. 2d 717-18.

It is not credible that Burns, Barbier, and Friedmann would not have been aware of simufilam's clinical trial results and the manipulated pre-clinical research, or that Burns kept the manipulations in the papers that she authored to herself, especially since she and Barbier were married. *See Makor Issues & Rts., Ltd. v. Tellabs Inc.*, 513 F.3d 702, 709-11 (7th Cir. 2008) ("Is it conceivable that [a defendant] was unaware of the problems of his company's two major products and merely repeating lies fed to him by other executives of the company? It is conceivable, yes, but it is exceedingly unlikely."); *also In re Triton Energy Ltd. Sec. Litig.*, 2001 WL 872019, at *10-*11 (E.D. Tex. Mar. 30, 2001) (rejecting defendants' argument "that position-and-experience evidence is incompetent as proof of scienter" and explaining that "most authorities have found [the] opposite").

The fact that the data was intentionally manipulated further "impl[ies] that the data was falsified and that Defendants ***knew*** so." *In re Fibrogen, Inc.*, 2022 WL 2793032, at *13 (N.D. Cal. July 15, 2022). ¶¶446-450; *also* ¶¶220-222, 241-244, 328-329. And Defendants invalidating adverse Phase 2b results on the basis of data "anomalies," but then concealing other significant anomalies in the purportedly positive reanalysis of that same data and Cassava's Phase 2a results further demonstrates their knowledge and recklessness. §II.B. *See In re Veeco Instruments, Inc. Sec. Litig.*, 235 F.R.D. 220, 231 (S.D.N.Y. 2006) (alleged actions contrary to prior practice, "'form the basis for proof of recklessness'").

2. By Publically Discussing the Data at Issue, Defendants Evidenced Their Knowledge or Recklessness

It is well-settled that "an inference of scienter can be established by the fact that the Defendants touched on the specific issue . . . in their public statements." *Roberti v. OSI Sys., Inc.*, 2015 WL 1985562, at *12 (C.D. Cal. Feb. 27, 2015). Contrary to their "group pleading" argument (Mot. at 27-28), each of the Defendants made and approved numerous specific statements, throughout the Class Period, regarding the very information that Plaintiffs' alleged was false or misleading, which evidences their knowledge of the

subject matter and further supports an inference of scienter.[15] In press releases, presentations and SEC filings, each Defendant repeatedly touted: (i) the Phase 2b reanalysis biomarker results (*see, e.g.*, ¶¶269-273, 275-276, 282, 284, 289, 294, 301, 306, 310); Phase 2b Spatial Memory test results (*see, e.g.*, ¶274); Phase 2b P-tau181 plasma biomarker results (*see, e.g.*, ¶¶312, 317); the Phase 2a trial results (*see, e.g.*, ¶¶259-266, 286, 294); and Cassava's preclinical research (*see, e.g.*, ¶¶277, 280-281, 289, 292). "The specificity of these statements . . . is ***strong*** circumstantial evidence that [speakers] were receiving some form of specific information . . . ." *City of Pontiac Gen. Emps.' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012).

"Given the statements that Defendants made about [a clinical trial] and its results . . . it is simply ***not plausible*** that Defendants did not know the results of both the positive and negative data regarding these endpoints. And this finding is supported by numerous authorities." *Voulgaris*, 2020 WL 8367829, at *2 (noting that an executive "'"bridge[s] the scienter gap" herself ***by referencing the data directly***"' and that "'[i]t is unclear what further facts plaintiffs would need to plead to create a stronger inference that she had access to information she discussed publicly'"). Importantly, "[t]his is not a case in which the purported knowledge depends only on 'corporate management's general awareness of the day-to-day workings of the company's business.'" *QuantumScape*, 580 F. Supp. 3d at 741. "Instead, the individual defendants

[15] *See In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 335 (S.D.N.Y. 2014) (where, as here, a small company "focused on the production of just one product" and approval of that product turned on its "performance in clinical trials" and the defendants' "public statements evinced a familiarity with the data in the trials," these allegations "taken together raise a strong inference that [defendants] knew and/or had access to facts [contradicting] their public statements regarding [a clinical trial]"); *Frater*, 996 F. Supp. 2d at 350 (finding scienter adequately pled where "defendants are sophisticated scientists running a regulated, publicly traded corporation" yet misleadingly "heralded scientific results which they knew to be the product of empirically faulty procedures and manipulated statistical analysis"); *Stone v. Life Partners Holdings, Inc.*, 26 F. Supp. 3d 575, 600 (W.D. Tex. 2014) ("when a company is a single-product company, like Life Partners, the gravity of misrepresentations about the product to the public is strong evidence that the 'danger was either known to the defendant or so obvious that the defendant must have been aware of it.'"). *See also Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 342 (5th Cir. 2008) (finding allegations to be probative of scienter where the alleged misrepresented information was sufficiently important to the health of the company).

personally reported facts about the company that are alleged to be completely at odds with reality." *Id.*

3. Defendants' Repeated Public Denials of the Citizen Petition Evidenced Their Knowledge or Recklessness

"Actual knowledge, though, is not required to create a strong inference of scienter. Rather, conduct that is severely reckless satisfies the scienter requirement under section 10(b)." *Stone*, 26 F. Supp. 3d at 599-600 (citing *Nathenson*, 267 F.3d 400). Just hours after learning of the Citizen Petition, Cassava publicly denied the petition's findings. §II.F.; ¶317. Defendants' abject failure to investigate the veracity of these allegations before dismissing them out of hand was, at a minimum, severely reckless and satisfies the scienter standard under §10(b).

"These denials indicate that [Defendants] were either sufficiently familiar with the facts, or severely reckless in not being familiar, to be in a position to issue a denial. As such, [Defendants'] denials demonstrate, at a minimum, extreme recklessness . . . ." *In re Sunbeam Secs. Litig.*, 89 F. Supp. 2d 1326, 1338 (S.D. Fla. 1999). *See Bond*, 587 F. Supp. 3d at 678 (a response to a short report that "confirmed many aspects of that Report and simply spun the revelations as untroubling, run-of-the-mill facts and circumstances of which Clover and its executives were already aware" indicative of scienter because the defendants essentially "represented to the public that they had kept abreast of the underlying matters").

Indeed, it would not have been possible for Cassava to have conducted a reasonable investigation of the Citizen Petition's findings in the few overnight hours between the petition's release and Cassava's statement ***without*** prior knowledge of the data manipulations and anomalies that the petition raised. ¶¶14, 316-317. *See also* ¶¶457-464. And Barbier later confirmed no real investigation had taken place prior to responding to the Citizen Petition when he stated on September 3 that "we ***don't have*** the original films or images for the Western blots in question." ¶¶20, 331-332, 458.

Defendants therefore either had the data in their possession, and thus knew it had been manipulated, or failed to obtain and verify it before issuing their response to the Citizen Petition, demonstrating their

recklessness. ¶¶459-464.[16] Accordingly, "[t]he only compelling, possible inference is that [Defendants] were either aware of the truth and intentionally misled investors . . . or were willfully blind and severely reckless in ignoring the truth." *ArthroCare*, 726 F. Supp. 2d at 718.

4. Defendants' Cover-Up Is Indicative of Scienter

Defendants' scienter is further supported by their unsuccessful attempts to pass off doctored images as original data to the *Journal of Neuroscience* and *Neuroscience* in order to obtain exculpatory statements from the journals, which Barbier and Schoen then used to issue press releases falsely stating that the journals confirmed there had been no data manipulation in Cassava's pre-clinical research. §II.G.; ¶¶451-453. Such "[a]ttempts to cover up fraud demonstrate a high degree of scienter." *Vanderhoef v. China Auto Logistics Inc.*, 2020 WL 5105243, at *3 (D.N.J. Aug. 31, 2020). *See In re Nature's Sunshine Prods. Sec. Litig.*, 486 F. Supp. 2d 1301, 1310 (D. Utah 2007) ("Evidence that a defendant has taken steps to cover-up a misdeed is strong proof of scienter.").

But Defendants' cover up did not end there. As alleged in the Complaint, Defendants removed negative information about Cassava and the Citizen Petition's allegations from a public website. *See* §II.G. In addition, Defendants deleted Cassava's Scientific Advisory Board webpage after ***its own members*** made clear that: (i) the Scientific Advisory Board did not meet; and (ii) experts Cassava ***continued*** to identify in SEC filings as advising the Company (like Sahakian) had not actually worked with Cassava in years. *Id*. These efforts to cover their tracks is further evidence of Defendants' scienter.

Last, contrary to Defendants' claim, Plaintiffs did not "blatantly misrepresent" Barbier's statement minimizing the FDA's response to the Citizen Petition. Mot. at 21. Defendants concede that Barbier stated:

[16] *See Bach*, 2016 WL 4443177, at *13 (finding severe recklessness where defendants failed to investigate alleged "'major improprieties'" in a short report and news article and instead sought to deny and delegitimize the allegations); *ArthroCare*, 726 F. Supp. 2d at 712 (W.D. Tex. 2010) (finding a strong inference of scienter where defendants "were directly confronted by the financial media with evidence of various fraudulent practices at ArthroCare," but "continued to reassure investors the reports were lies, rumor-mongering, and propaganda by short sellers" or otherwise by their "silence" allowed the misrepresentations).

"[W]hat the FDA says is ***there is no evidence***" of fraud. *Id*. Barbier's statement is false. The FDA never said there was "no evidence" supporting the Citizen Petition's findings. §II.I. To the contrary, the FDA "acknowledged the importance of the issues" raised, but denied the petition "***solely***" on technical grounds, taking special care to note that its decision "***does not represent a decision by the Agency to take or refrain from taking any action relating to the subject matter of your Petitions***." ¶411. Indeed, an analyst present when Barbier made the statement agreed it was misleading. *See* §II.I. Barbier's misleading characterization of the FDA's response to the Citizen Petition also supports his scienter.

5. Cassava's Bonus Plan and Offerings Incentivized Defendants to Commit Fraud and Are Probative of Scienter

Regardless of whether their scheme was successful, Defendants were incentivized to inflate Cassava's stock price with false and misleading statements to reap significant financial gains, and "'personal financial gain may weigh heavily in favor of a scienter inference.'" *Stone*, 26 F. Supp. 3d at 600 (quoting *Tellabs*, 551 U.S. at 325). But as the Supreme Court has recognized, "[w]hile it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, . . . the ***absence*** of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 325 (2007).

Defendants created Cassava's cash bonus plan, tying the bonus to Cassava's near-term stock price, just weeks before the Company announced the false and misleading Phase 2b reanalysis results (and while Defendants were already in possession of those results). §II.C. This change qualified Defendants Barbier, Friedman, and Schoen and other executives and directors to reap nearly ***two hundred million dollars*** in bonus payments during the Class Period. These massive bonus payments were not based on any meaningful product development milestones. Rather, the bonus payments were based entirely on short-term increases in Cassava's stock price, thereby incentivizing Defendants to inflate the Company's stock price. *Id*. And Burns, as Barbier's wife, also stood to benefit.

These nefarious circumstances set them apart from typical compensation practices that may not raise an inference of scienter. *See Stone*, 26 F. Supp. 3d at 607 ("unusual" compensation practices

indicative of scienter); *Evanston Police Pension Fund v. McKesson Corp.*, 411 F. Supp. 3d 580, 603 (N.D. Cal. 2019) (correlation between company's financial performance and large cash awards support a finding of scienter); *Frater*, 996 F. Supp. 2d at 350 (personal incentives and alterations to bonus plan that depart from executives' typical compensation incentives supports scienter); *also Barrie*, 397 F.3d at 261 (bonus received for achieving targeted revenues supported inference of scienter).

Defendants denigrate Plaintiffs' motive allegations as "absurd." Mot. at 25. But Defendants' short-term need to keep their stock price inflated in order to reap financial gains and obtain much needed operating capital provides a plausible motive for Defendants' actions, and supports a finding of scienter. *See In re Portal Software, Inc. Sec. Litig.*, 2005 WL 1910923, at *12 (N.D. Cal. Aug. 10, 2005) ("[P]laintiffs' contention that defendants were motivated to inflate artificially Portal's stock price in the short term in order to conduct a successful secondary public offering and obtain much-needed operating capital does allege facts of a palpable motive for fraud."). Indeed, Cassava was on the cusp of announcing "***significant*** multi-year capital inflows" from an unnamed source when the Citizen Petition was disclosed, derailing the funding. ¶474.

That Defendants' fraud was partially revealed before they received their bonuses does not negate the inference of scienter. *See Tellabs*, 513 F.3d at 710 ("The fact that a gamble – concealing bad news in the hope that it will be overtaken by good news – fails is not inconsistent with its having been a considered, though because of the risk a reckless, gamble."). Nor do Defendants' stock holdings negate the inference of scienter, as Defendants obviously did not orchestrate the unforeseen filing of the Citizen Petition that caused Cassava's share price to decline. Mot. at 25. Moreover, the cash bonus plan allowed Defendants to profit regardless of the long-term value of Cassava's stock price. Indeed, Barbier previously became rich off shareholder money despite driving Pain Therapeutics (and its share price) into the ground. §II.A. Cassava was simply his "latest cash grab." *Id*.

Defendants also had a strong financial incentive to keep Cassava's share price inflated throughout

the Class Period to access necessary operating capital. By inflating Cassava's stock price, Defendants raised $275 million in capital during the Class Period ***needed*** to fund simufilam's continued development and fill its executive's bonus pool. §II.C. "These allegations separate Plaintiffs' case from the 'generalized corporate motive' cases relied upon by Defendants . . . ." *Voulgaris*, 2020 WL 8367829, at *25. *See Frater*, 996 F. Supp. 2d at 350 (where company "was allegedly sufficiently short on cash at the time of the alleged misrepresentations that it could not afford to finance an additional clinical trial" thereby "heightening its need for a lucrative stock sale" provides motive probative of scienter); *McDermid v. Inovio Pharms., Inc.*, 520 F. Supp. 3d 652, 664 (E.D. Pa. 2021) (pharmaceutical company's motive "to raise capital through at-the-market stock offerings" where it had no source of income "helps Plaintiffs' scienter claims survive dismissal"). Thus, Plaintiffs' allegations "that 'defendants were motivated to inflate artificially [their company's] stock price in the short term . . . and obtain much-needed operating capital does allege facts of a palpable motive for fraud,' as it goes beyond 'the generic desire to raise capital which can be attributed to every company.'" *MannKind*, 835 F. Supp. 2d at 813.

6. Defendants Recklessly Failed to Disclose Wang's Conflicts of Interest and the Scope of the Government Investigations

There is no dispute that Defendants were aware at the time they made their alleged false and misleading statements of the DOJ, SEC, and NIH investigations or that Wang had conducted the Phase 2b reanalysis and was financially conflicted. ¶¶366, 455. Defendants also knew that the NIH's had decided to stop funding at the time of their November 15, 2021 statement given that NIH made its decision following the Citizen Petition's release in August 2021. Fn. 4, *supra*. *See In re NetSolve, Inc. Sec. Litig.*, 185 F. Supp. 2d 684, 697 (W.D. Tex. 2001) (scienter adequately pled where undisclosed information "so obvious" defendants must have been aware of it). Defendants' failure to disclose the scope and focus of the investigations, including the NIH's withholding of funds, demonstrates their scienter. *See Menaldi*, 164 F. Supp. 3d at 585 (executives "reckless in opting to misrepresent their exposure to civil and criminal

liability").[17] Likewise, Defendants' concealment of Wang's involvement in the Phase 2b reanalysis and his conflicts of interest – in contrast to the Company's prior practice, where Wang's involvement was disclosed – supports an inference of scienter. *Supra*, §II.B.; ¶¶454-456. *See In re Veeco*, 235 F.R.D. at 231 ("alleged actions, which are contrary to expressed policy and prior practice, 'form the basis for proof of recklessness'").[18]

7. Additional Evidence of Scienter

Defendants' prior fraudulent conduct further supports a strong inference of scienter. Barbier and Friedmann had a history of making misleading statements, which included an FDA reprimand for misleading marketing practice (¶475) and settling a similar securities fraud class action on the eve of trial after the court held that there was sufficient evidence for a jury to find that Barbier and Friedmann knowingly misled investors. ¶¶77, 477-478. *See In re Enron Corp. Sec., Derivative & ERISA Litig.*, 235 F. Supp. 2d 549, 693 (S.D. Tex. 2002) ("[T]he scienter pleading requirement is partially satisfied by allegations of a regular pattern of related and repeated conduct."); *Austin v. Loftsgaarden*, 675 F.2d 168, 180 (8th Cir. 1982) (holding in securities fraud action that trial court properly admitted evidence of defendant's prior fraud as probative of intent).[19]

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[17] The ongoing government investigations are themselves probative of scienter, as well. *See In re Akorn, Inc. Sec. Litig.*, 240 F. Supp. 3d 802, 820 (N.D. Ill. 2017) ("That the SEC and DOJ initiated investigations provides additional support for finding that scienter has been adequately pleaded.").

[18] Defendants' cases are readily distinguishable. Mot. at 27-28. In *Local 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Diodes, Inc.*, 810 F.3d 951, 958 (5th Cir. 2016), unlike here, defendants repeatedly informed investors on the issues that were allegedly concealed. In *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 867-68 (5th Cir. 2003) and *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 433 (5th Cir. 2002), plaintiffs' allegations of scienter were based on hindsight and defendants' failure to foresee future events. Here, Defendants were aware of the information ***at the time*** they made their alleged false and misleading statements. In *In re Plains All Am. Pipeline, L.P. Sec. Litig.*, 245 F. Supp. 3d 870, 923-27 (S.D. Tex. 2017), unlike here, the plaintiff's bare allegations that senior executives at a massive oil company must have known about problems on two discrete sections of pipeline constituting just ***0.008%*** of its overall pipeline network were insufficient.

[19] *In re Dell, Inc. Sec. Litig.*, 591 F. Supp. 2d 877, 905 (W.D. Tex. 2008) is distinguishable as the "four matters Plaintiffs reference involve[d] entirely different companies." Here the prior securities fraud class action concerned the same defendants as in this case (Barbier, Friedman, and Cassava's predecessor

C. Loss Causation Is Adequately Pled

In the Fifth Circuit, loss causation allegations are subject to Rule 8's liberal pleading standards and need merely "'provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind.'" *Amedisys*, 769 F.3d at 321. To plead loss causation, Plaintiffs thus need allege only enough facts to show a "facially 'plausible' causal relationship between the [alleged] fraudulent statements or omissions and [Plaintiffs'] economic loss . . . followed by the leaking out of relevant or related truth about the fraud that caused a significant part of the depreciation of the stock . . . ." *Lormand*, 565 F.3d at 258. Plaintiffs readily satisfy the standard.

The Complaint alleges that Defendants made a series of false and misleading statements regarding the integrity of their pre-clinical research and Phase 2a and 2b clinical trial results and the scope of criminal and civil investigations into those results. Investors learned the truth through a series of partial disclosures. ¶¶497-506. Following each partial disclosure, Cassava's stock price fell significantly. *Id*. These allegations are more than sufficient to meet the liberal Rule 8(a) pleading requirement for proximate cause and nothing more is required. *See, e.g.*, *Amedisys*, 769 F.3d at 326 (finding that loss causation is properly pled where the complaint "sets forth specific allegations of a series of partial corrective disclosures, joined with the subsequent fall in [the company's] stock value"); *Cobalt*, 2016 WL 215476, at *6 (finding that allegations of stock price declines of 21%, 11%, and 11.5% after partial disclosures were sufficient to show loss causation); *Parmelee v. Santander Consumer USA Holdings, Inc.*, 2018 WL 276338, at *6 (N.D. Tex. Jan. 3, 2018) (allegations that "company's stock price dropped" twice upon release of fraud-related information sufficient).

Because Defendants do not dispute that each partial corrective disclosure related to the alleged fraud or that those disclosures caused the stock to decline, loss causation is sufficiently pled. *Lormand*, 565 F.3d at 258. Nevertheless, Defendants recycle arguments regarding the falsity of particular statements,

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company, Pain Therapeutics) and similar allegations.

contending that disclosures of "unadjudicated" accusations of wrongdoing cannot constitute a corrective disclosure. Mot. at 31. But "Defendants' argument would mean that loss causation could only be proven through a criminal conviction – the point at which the fraud is no longer 'speculative.' ***But that is not the law***." *Utesch v. Lannett Co., Inc.*, 385 F. Supp. 3d 408, 425 (E.D. Pa. 2019); *Amedisys*, 769 F.3d at 324-25 ("'To require, in all circumstances, a conclusive government finding of fraud merely to plead loss causation would effectively reward defendants who are able to successfully conceal their fraudulent activities by shielding them from civil suit.'"). Accordingly, "'there is no requirement that a corrective disclosure take a particular form or be of a particular quality. . . . It is the exposure of the fraudulent representation that is the critical component of loss causation.'" *Id.* at 323-24.

As a result, the Fifth Circuit has held that, like here, a series of partial disclosures, including a short seller report, news article and subsequent announcement of SEC and DOJ investigations, followed by a drop in the company' stock price, are together sufficient to plead loss causation, especially where, like here, the company attempted to "mitigate" the impact of the short report. §§II.F.-G.; II.I.; ¶¶331-333. *See Amedisys, Inc.*, 769 F. 3d at 323-325; *also In re Eros*, 2021 WL 1560728, at *9 (crediting allegations based on a short seller report); *Snellink*, 870 F. Supp. 2d at 942 (same); *Bond*, 587 F. Supp. 3d at 680 (same); *In re QuantumScape*, 580 F. Supp. 3d at 742 (finding loss causation adequately plead when "[i]mmediately after both [an analyst article and short seller report] were published, QuantumScape's stock price plummeted"); *Franchi*, 2022 WL 4594575, at *20 ("allegations" brought by experts in a complaint sufficiently credible to plead a corrective disclosure). Defendants cannot escape liability for fraud simply by not admitting the fraud.[20]

[20] Defendants cite ***no*** authority holding that short seller reports, news articles or even opinions or allegations may not be considered corrective for loss causation purposes. For example, in *Janbay v. Canadian Solar, Inc.*, 2012 WL 1080306, at *15-*16 (S.D.N.Y. Mar. 30, 2012), the alleged corrective disclosures were not related to the fraud, which is not an argument Defendants make here. Further, Defendants' assertion that the disclosure of an investigation, absent an actual revelation of fraud, is not a corrective disclosure (Mot. at 32) is "wholly without merit." (*Bond*, 587 F. Supp. 3d at 680) because, here,

Defendants' other argument that the alleged partial corrective disclosures subsequent to the Citizen Petition merely restate "accusations that were already then public and therefore" fail to disclose any "new" information that could form a valid corrective disclosure is "a dispute of fact that [a court] cannot resolve on a motion to dismiss." *Franchi*, 2022 WL 4594575, at *21. Further, Defendants offer no argument on this issue, other than the conclusory statement that no "new" information was disclosed in the Citizen Petition supplements, Dr. Bik's findings and the *New York Times* article (Mot. at 34), but that is not grounds for dismissal. *See Amedisys*, 769 F.3d at 325 (Defendants' arguments attacking the validity of corrective disclosures "is a highly fact intensive inquiry that need not be reached at this point."); *Lormand*, 565 F.3d at 267 n.35 (noting "several circuit courts and district courts point out that it is often inappropriate to use a Rule 12(b)(6) motion as a vehicle to resolve disputes over 'loss causation'"); *see also Holzwasser*, 2006 WL 897746, at *4 ("Defendants' arguments are fact-based and are insufficient to support a motion to dismiss."). Each of those disclosures not only corroborated the prior disclosures, but disclosed additional, previously undisclosed data manipulations, anomalies and information undermining the reliability of Defendants' research. ¶¶328-330, 372-379, 380-385, 425-432. Notably, Defendants offer no explanation as to why Cassava's stock price repeatedly dropped in response to this news if it had already been disclosed to the market.[21] Plaintiffs have more than adequately pled loss causation.[22]

V. CONCLUSION

For these reasons, Defendants' Motion should be denied. If the Court grants Defendants' Motion, Plaintiffs respectfully request leave to amend.

Plaintiffs have also alleged that the revelation of the investigations were corrective of Defendants' misstatements concealing the extent and scope of those investigations, an additional and separate basis for loss causation.

[21] Plaintiffs do not allege that the August 25, 2021 Cassava press release is a corrective disclosure, contrary to Defendants' assertion.

[22] Defendants request dismissal of the §20(a) claims on the basis that Plaintiffs fail to adequately plead an underlying §10(b) violation. Mot. at 35. Because Plaintiffs adequately allege their §10(b) claims, Defendants' motion to dismiss the §20(a) claims should be denied.

DATED: December 23, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on December 23, 2022, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the email addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

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